IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION
TO EXCLUDE THE OPINIONS AND TESTIMONY OF SHELBY THAMES, PH.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this response to Plaintiffs' Motion [ECF 2018 (Pls.' Mot.)] and Memorandum of Law in Support of Defendants' Motion to Exclude the Opinions and Testimony of Shelby Thames, Ph.D. [ECF 2039 ("Pls.' Mem.")] (together, the "Motion"). The cases to which this Response applies are identified in Ex. A.

INTRODUCTION

Dr. Shelby Thames is a polymer chemist who earned a Ph.D. in organic chemistry in 1964. Concurrently with his Ph.D. training, Dr. Thames minored in analytical chemistry, *i.e.*, the study of the methods, techniques, and equipment used to evaluate chemicals. Upon graduation, Dr. Thames joined the chemistry department at the University of Southern Mississippi ("USM").

In 1969, Dr. Thames founded the Department of Polymer Science at the USM. Two years later, he began serving as dean of the College of Science as well. In 1986, Dr. Thames was designated Distinguished University Research Professor of Polymer Science, a position he has held since that time. Dr. Thames is also a member of the American Chemical Society—a national organization of chemists for which Dr. Thames has taught courses and given

presentations—as well as the American Institute of Chemists and the American Association of Advancement of Science.

Throughout his career, Dr. Thames has taught chemistry and polymer science—including the chemical characteristics of polymers like polypropylene—to undergraduates, Ph.D. candidates, and post-doctoral fellows. In addition, Dr. Thames has extensive experience designing polymers for various uses, with a specialization in polymeric coatings. His research involves adhesives, hydrocarbon materials, as well as biological materials including proteins and lipids. He has published extensively in peer-reviewed journals, and given numerous presentations on his findings.

Plaintiffs recognize that Dr. Thames has previously testified before this Court. Motion at 1, 3. Notably, Plaintiffs do not challenge all of Dr. Thames's opinions in this litigation. Rather, the Motion is limited to "new areas of testimony that were not addressed previously." Motion at 3.[1]

Plaintiffs challenge Dr. Thames's opinions regarding Ethicon's seven-year dog study. In particular, Plaintiffs claim that Dr. Thames's opinions (i) conflict with the conclusions reported in the dog study; (ii) misstate the evidence from the dog study; and (iii) are not based on data reported in the dog study. Motion at 3-6. As discussed below, however, Plaintiffs misunderstand and ignore Dr. Thames's opinions regarding the dog study, as well as the scientific bases for his opinions.

Plaintiffs also assert that Dr. Thames's opinions regarding the chemical composition of the translucent coating and flakes he has observed on Prolene explants are unreliable because he

[1] Dr. Thames has previously testified before this Court about the dog study. Pls.' Motion Ex. B, *Huskey* 9/2/14 Trial Tr. 36:16-50:11 (testifying about the dog study, including his opinions that the dog study data show improved physical properties like toughness, and no loss of molecular weight); *see also id.* 46:20-47:15 (testifying about the same stress-strain curve depicted in the Report in this litigation).

did not cite scientific literature proving his opinion. Motion at 6-7. Plaintiffs' argument omits the fact that Dr. Thames's opinions are based on reliable and repeatable scientific testing.

Finally, Plaintiffs argue that Dr. Thames's opinions based on his analysis of mesh explants are unreliable because his cleaning process eliminated any evidence of oxidation, and he failed to validate his cleaning process with a control. However, the scientific method does not require a control when there is no variable at issue. Plaintiffs also fundamentally misunderstand the science underlying Dr. Thames's cleaning protocol.

Tellingly, Plaintiffs do not cite any scientific evidence to support their challenges to Dr. Thames's opinions. In striking contrast, Dr. Thames's opinions are based on his knowledge, education, training, and experience as a polymer chemist for over 50 years; his review of relevant scientific literature; and his scientific analysis of mesh explants using reliable and repeatable scientific methods. As discussed, in greater detail below, Plaintiffs' arguments are without merit, and the Court should deny Plaintiffs' Motion.

ARGUMENT

I. Plaintiffs Misunderstand Dr. Thames's Opinions Regarding the Dog Study.

Plaintiffs assert that Dr. Thames's Report "is at conflict with itself," because Dr. Thames relies on Ethicon's seven-year dog study ("dog study") to support his opinions that Prolene is not subject to *in vivo* degradation. Motion at 3. Similarly, Plaintiffs claim that the dog study contradicts Dr. Thames's opinion that he has "seen no scientifically sound evidence to prove Ethicon's Prolene mesh oxidizes *in vivo*." *Id.* at 4. Plaintiffs' arguments oversimplify and misinterpret Dr. Thames's opinions, as well as his reliance on the dog study.

Dr. Thames certainly relies on the dog study to support his opinion that Prolene is not subject to oxidative degradation *in vivo*. *See* Pls.' Motion Ex. C, Expert Report of Shelby F. Thames, Ph.D. ("Thames Report") at 6 [ECF 2039-3] (explaining that the "seven year data

confirmed no significant difference in molecular weights," and that the dog study's "physical property determinations via measurements of tensile strength, elongation and Young's modulus . . . are extremely valuable data"); *id.* at 6 (reporting that the tensile strength and elongation data from the dog study demonstrate that Prolene's "physical properties improved"); *id.* at 7 (noting that the dog study's "molecular weight determinations by Gel Permeation Chromatography" showed "no meaningful change" over the course of the study). *Id.* at 8. But even a superficial examination of Dr. Thames's Report and testimony reveals that he does not rely on the narrative conclusions formed by Daniel Burkley, an Ethicon scientist who participated in the study or all of the methodological decisions made during the study. *See, e.g., id.* at 6 (noting that Burkley's conclusions regarding FTIR data are inconsistent with scientific literature). Rather, Dr. Thames uses his extensive education, training, and experience as a polymer chemist, as well as information gleaned from his review of relevant scientific literature, to form his opinions based on the data and findings reported in the dog study.

A. Dr. Thames disagrees with the dog study's conclusion that FTIR data showed "possible evidence of oxidation."

Plaintiffs misunderstand the significance of Dr. Thames's statement that he has "seen no *scientifically sound* evidence to prove Ethicon's Prolene mesh oxidizes *in vivo*." Motion at 4 (emphasis added). Indeed, not only is Dr. Thames aware of the inconsistency between his opinion regarding oxidation and Mr. Burkley's "possible" conclusion in the dog study, but he explained the scientific bases for that disparity in his Report.

Dr. Thames clearly opines that Mr. Burkley erred in noting in the dog study that "a broadened weak absorbance at about 1650 cm^{-1}" was "possible evidence of oxidation." Thames Report at 6 (stating that Burkley "mis-assign[ed]" the FTIR frequency). According to Dr.

Thames, the relevant scientific literature shows that Mr. Burkley's FTIR data actually revealed that proteins were adhered to the surface of the fibers under examination. *Id.*

Specifically, Dr. Thames notes that scientific literature has established an absorption frequency of 1740 cm^{-1} for oxidized polypropylene. Pls.' Motion Ex. C, Thames Report at 22-23 (observing that the Wood study shows that oxidized polypropylene exhibits a carbonyl peak at 1740 cm^{-1}). Dr. Thames also explains that studies show that FTIR absorption frequencies of 1650 cm^{-1} indicate the presence of proteins, not Prolene oxidation. *Id.* at 22-24; *see also* J. Kong & S. Yu, *Fourier Transform Infrared Spectroscopic Analysis of Protein Secondary Structures*, 39 Acta Biochimica et Biophysica Sinica 549, 550 (2007) (noting that "Amide I" proteins exhibit carbonyl stretching with FTIR absorption frequencies of 1600-1690 cm^{-1}).

Significantly, Dr. Thames points out that the dog study contained no indication that proteins had been cleaned from the fibers prior to examination. Pls.' Motion Ex. C, Thames Report at 6. Indeed, as Mr. Burkley reported, "[m]ost of the[] specimens were still surrounded by some tissue[.]" Ex. B, ETH.MESH.09888189.

Thus, although he does not dispute that Mr. Burkley observed a carbonyl peak at 1650 cm^{-1}, Dr. Thames explains that the application of sound scientific methods dictates that this carbonyl peak shows the presence of proteins adhered to the surface of the fiber following implantation. Pls.' Motion Ex. C, Thames Report at 6. Despite Plaintiffs' argument to the contrary, Dr. Thames's statement that he has "seen no scientifically sound evidence" of *in vivo* oxidation of Prolene is entirely consistent with his opinions in this litigation, as well as the relevant scientific literature.

B. Dr. Thames's opinion that dog study erroneously reported signs of Prolene degradation is based on fundamental principles of polymer chemistry.

Turning to Plaintiffs' argument regarding degradation, although Dr. Thames does not dispute that Mr. Burkley reported that "[d]egradation in Prolene is still increasing [over time *in vivo*]," he opines that Mr. Burkley's conclusion is at odds with fundamental principles of polymer science.

As Dr. Thames explains in his Report, the scientific literature establishes that a polymer undergoes oxidative degradation only when there has been (i) formation of carbonyl groups consistent with oxidation; (ii) a loss of molecular weight; and (iii) a loss of physical properties, including tensile strength, elongation, and toughness. *See* Pls.' Motion Ex. C, Thames Report at 7-10, 26-28; *see also* Ex. C, G. Wypych, Handbook of Material Weathering, 424-27 (2008) (advising that an increase in carbonyl concentration and decrease in molecular weight will accompany any oxidative degradation of polypropylene); Ex. D, H. Zweifel, *et al.*, Plastics Additives Handbook, *Antioxidants*, at 5-6 & Scheme 1.3 (2009) (reporting that degradation is accompanied by mechanical deterioration, molecular weight changes, molecular weight distribution changes, and an increase in carbonyl groups); Ex. E, M. Gahleitner & J. Fiebig, Polypropylene: An A-Z Reference, *Long Term Properties and Lifetime Prediction for Polypropylene*," 394 (1999) (explaining that degradation "reduc[es] the average chain length of the polymer and especially affecting the high molar weight fraction" which cause "a significant reduction of mechanical properties," including "embrittlement" and "a massive decrease in toughness"). Because the data in the dog study did not satisfy any of these criteria, Dr. Thames opines that Mr. Burkley's conclusion is not scientifically supportable.

As discussed above, although Mr. Burkley reported evidence of carbonyl peaks in FTIR data, the scientific literature demonstrates that the carbonyl peaks he observed reveal the

presence of proteins, not oxidation. *See supra* Part I.A. With respect to molecular weight, Dr. Thames observes throughout his Report that the dog study reported no meaningful loss of molecular weight. Pls.' Motion Ex. C, Thames Report at 8 (reporting that GPC analysis showed "no meaningful change" in molecular weight over the course of the dog study); *see also* Ex. B, ETH.MESH.09888218-22 (reporting molecular weight determinations made in 1992 using GPC). Finally, as Dr. Thames repeatedly notes in his Report, the data from the dog study do not show a decrease in physical properties; rather, the dog study data confirm a substantial increase in toughness. Pls.' Motion Ex. C, Thames Report at 7-8; *see also infra* Part III.

Despite Dr. Thames's clear statements regarding the dog study—including his disagreement with certain aspects of the study—Plaintiffs tellingly choose to ignore his opinions. Nor do they present any scientific evidence refuting his opinions. Indeed, Plaintiffs eschew science altogether, and instead focus on "conflict[s]" that Dr. Thames identified and addressed in his Report and testimony. Plaintiffs' arguments are without merit, and the Court should deny Plaintiffs' Motion on this issue.

II. Dr. Thames Properly Bases His Opinion That Prolene Does Not Degrade *In Vivo* On the Molecular Weight Data Reported in the Dog Study.

Plaintiffs claim that Dr. Thames "misstates the evidence from the dog study in order to fit his opinions." Motion at 4. Specifically, Plaintiffs assert that Dr. Thames should be precluded from testifying that the dog study showed no loss of molecular weight because there is "no evidence that Prolene's molecular weight was unchanged[.]" *Id.* at 5. Plaintiffs fail to understand the science underlying Dr. Thames's opinions.

Dr. Thames bases his opinion that he has seen no evidence of *in vivo* degradation of Prolene, in part, on the molecular weight data from the dog study. *See* Pls.' Motion Ex. C, Thames Report at 6, 8-10. Specifically, the dog study reported the following molecular weight

data after the fibers at issue had been implanted for seven years:

Specimen	**Mw**	**Mn**
Prolene 4/0 (control)	324,000	60,000
Site 1 Dog #2007	322,000	69,000
Site 6 Dog #2007	323,000	63,000
Site 3 Dog #1995	327,000	59,000
Site 3 Dog #2019	331,000	64,000
Site 2 Dog #2019	332,000	57,000
Site 2 Dog #2008	322,000	53,000

See Ex. B, ETH.MESH.09888218-22 (reporting molecular weight determinations made in 1992 using GPC). As Dr. Thames repeatedly opines in his Report, based on his education, training, and experience as a polymer chemist, these data show that the molecular weight changes in the sutures were not meaningful. Pls.' Motion Ex. C, Thames Report at 6, 8-10, 26-28.

Dr. Thames's opinion is confirmed by the fact that there was no deterioration in physical properties, as the scientific literature shows accompanies a scientifically significant loss of molecular weight. *See e.g.*, Ex. E, Gahleitner at 394. To the contrary, the dog study data show an increase in toughness. *See* Pls.' Motion Ex. C, Thames Report at 7-8; *see also infra* Part III.

Plaintiffs notably cite no scientific evidence whatsoever to support their contention that the changes in molecular weight reported in the dog study—some of which were actually increases—are scientifically significant.

Moreover, Plaintiffs forget that their own expert—Dr. Howard Jordi—previously performed similar molecular weight studies via GPC on 15 patient explanted samples and several

control Prolene samples, and confirmed the findings of the dog study. *See* Ex. F, Expert Report of Dr. Howard Jordi, at 84 (May 20, 2014). Dr. Jordi reported that "[t]he control and explant samples do no show a significant difference in molecular weight." *Id.* Indeed, he conceded that the "Jordi GPC analysis of both control and explant samples tends to confirm 'The 7 Year Dog Study' performed at Ethicon . . . in that little to no macro MW degradation was noted." *Id.* at 10.

Unencumbered by any form of scientific evidence, Plaintiffs seek to substitute their beliefs for the education, training, and experience Dr. Thames has acquired over the course of the last 52 years practicing as a polymer chemist. The Court should reject Plaintiffs' unsupported argument, and deny Plaintiffs' Motion on this issue.

III. Dr. Thames's Opinions That Prolene Increases in Toughness Following Implantation is Grounded in Sound Scientific Methods.

Plaintiffs assert that Dr. Thames's opinion that Prolene increases in toughness following implantation is "not true" because "the data required for those determinations was *never recorded*." Motion at 5 (emphasis in original). Plaintiffs claim is simply false.

As Dr. Thames reports, polymer chemists routinely assess the "toughness" of a material by analyzing the relationship between the force required to break the material—known as tensile strength or stress—and the extent a material lengthens before it ruptures—known as elongation or strain. Pls.' Motion Ex. C, Thames Report at 7. When these data points are plotted along the x- and y-axes of a graph, the area under the resulting curve defines the material's toughness. *Id.*

Applying this foundational concept of polymer chemistry to the data from the dog study, Dr. Thames found that Prolene's toughness improved after implantation. Specifically, Dr. Thames analyzed data collected in the dog study at years 0, 1, 2, and 7, where each data point represented an average of five determinations as required by ASTM protocols. *See* Ex. G, Data Summary of Ten Year Prolene BSR Study, ETH.MESH.11336182-83 ("BSR Data Summary").

Dr. Thames then plotted this data to create a stress-strain curve for the seven-year duration of the study, and incorporated this curve in his Report. Thames Report at 8. Based on this work, Dr. Thames concludes that the area under the stress-strain curve increased over time, meaning that toughness increased over time. *Id.* at 7-8.

Grasping at straws, Plaintiffs argue that the dog study did not record the data necessary to compute toughness values, and that Dr. Thames's analysis is not a stress-strain curve, but a "break-strength-percent elongation curve" which has no relationship to toughness. Motion at 6. Plaintiffs' assertion is simply wrong, and underscores Plaintiffs' misunderstand of basic polymer science and polymer testing fundamentals.

The dog study does indeed include recorded stress-strain data including modulus, breaking strength (or, "stress"), and elongation (or, "strain"), which were generated during tensile testing of pristine and explanted sutures. *See* Ex. G, BSR Data Summary, ETH.MESH.11336182-83. Modulus, by definition, is a *series* of stress-strain data that originates from the origin (*i.e.,* point 0,0 on a graph), and defines the elastic (*i.e.,* linear) behavior of the tested material. *See* Ex. H, J. Gere & S. Timoshenko, *Mechanics of Materials*, 14 (1997) (explaining that modulus is the "slope of the straight line" between the origin and the point on the curve at which stress and strain cease to have a proportional relationship). The breaking strength and the elongation at the breaking point define the ending point of the same stress-strain relationship. *See id.* at 14-15 (explaining the correlation between breaking strength and elongation).

By analyzing the origin point, the recorded modulus, the recorded breaking strength, and the recorded elongation, and applying fundamental principles of polymer mechanics, Dr. Thames constructed a representative stress-strain behavior for the fibers tested in the dog study. *See* Pls.'

Motion Ex. C, Thames Report at 7-8; *see also* Ex. H, Gere, at 14-15 (explaining the relationship among the components of a stress-strain curve); Ex. I, F. Miller & H. Doeringsfeld, *Mechanics of Materials*, at 22-24 (same).[2] He then used these stress-strain curves to compare the toughness of the fibers, and found that the fibers that had been implanted for seven years exhibited almost twice as much toughness as pristine exemplars. *See* Pls.' Motion Ex. C, Thames Report at 8.

Dr. Thames's approach is not simply conjecture, as it has been practiced in the plastics industry for decades. Indeed, modulus, breaking strength, and elongation are routinely reported in this manner on technical data sheets of commercially available polymers to represent the material's stress-strain behavior. *See, e.g.*, Ex. J, Prospector INEOS PP H00G-00 Technical Data Sheet (listing values for tensile strength, tensile elongation, and modulus); Ex. K, Sabic PP PCGH10 Technical Data Sheet. It is customary for scientists and engineers to deduce toughness from data sheet tensile properties.

Dr. Thames's conclusion is buttressed by the fact that the dog study data shows that fibers that had been implanted for seven years stretched approximately twice as much as pristine fibers when analyzed under identical tensile-testing conditions. *See* Ex. B, BSR Data Summary, ETH.MESH.11336182-83; *see also* Pls.' Motion Ex. C, Thames Report at 8. This doubling in the fiber's ability to stretch is completely consistent with the significant increase in the computed toughness values.

Plaintiffs do not point to any scientific support for their position. Rather, they merely regurgitate the testimony of their own expert, who claimed at deposition that he could not assess

[2] The fact that the breaking strength value is in units of pounds (rather than pounds per square inch or psi) is of no consequence in the context of computing toughness values for these data since the conversion from pounds to psi is simply achieved by dividing the breaking strength values by a constant (fiber cross sectional area). *See* Ex. H, Gere, at 4-5 (explaining calculation of stress). The relative change in toughness between pristine and explanted fibers remains the same regardless of whether that constant (fiber cross sectional area) is included in the computation.

toughness from Dr. Thames's stress-strain curve. Motion at 6 n.11 (citing testimony of Plaintiffs' expert, Dr. Scott Guelcher). But Dr. Guelcher also failed to identify any scientific support for his assertion. In other words, Plaintiffs' claim is based solely on their expert's *ipse dixit*.

Because Dr. Thames's opinion is the product of proper scientific methods, and Plaintiffs failed to ground their argument in reliable science, the Court should deny Plaintiffs' Motion on this issue.

IV. Dr. Thames's Opinions Regarding the Composition of the "Translucent Flakes" Coating Mesh Explants Are the Product of Reliable Testing.

Plaintiffs contend that Dr. Thames should be precluded from testifying that the translucent flakes he has observed on explanted Prolene fibers are proteins because he purportedly "cannot cite to any literature or support for that opinion[.]" Motion at 6. In support of their argument, Plaintiffs point to opinions Dr. Thames offered in the *Stubblefield* case. Motion at 6-7 (citing Dr. Thames's deposition testimony in *Stubblefield v. Ethicon, Inc.*, Case No. 2:12-cv-00842).[3] Plaintiffs' arguments ignore the fact that Dr. Thames developed his opinions using reliable and verifiable testing methods.

Dr. Thames's case-specific report in *Stubblefield* includes photomicrographs of a mesh explant which showed translucent flakes on the surface of the mesh fibers. *See* Ex. L, Thames Expert Report (*Stubblefield*) at 4-5 & figs. 4-5.[4] In order to determine the composition of these flakes, Dr. Thames analyzed the mesh fibers using techniques generally accepted in the field of

[3] Although Plaintiffs focus on the opinions Dr. Thames offered in *Stubblefield*, Dr. Thames testified in that case that he has made the same findings and conclusions "in 19 other cases just like this." Pls.' Motion Ex. H, Thames Dep. (*Stubblefield*) Tr. 48:17-18.

[4] Because Plaintiffs framed the issue using Dr. Thames's opinions in the *Stubblefield* case, this Response refers to his opinions and analysis as recorded in his case-specific report in that case. Note, however, that Dr. Thames's Report contains a similar analysis using the same protocol through which Dr. Thames reaches the same conclusions. *See* Pls.' Motion Ex. C, Thames Report at 95-114.

polymer chemistry: light microscopy, scanning electron microscopy ("SEM"), and Fourier Transform Infrared Spectroscopy ("FTIR"). *See id.* at 5-12 (discussing testing process). On the basis of this testing, Dr. Thames found that the "Prolene fiber" in the photographs "is encased within [a] dry, and cracked proteinaceous layer[.]" *Id.* at 4 (noting that the protein "structures were confirmed by FTIR microscopy.").

Specifically, Dr. Thames tested Prolene fibers from a pristine exemplar and a mesh explant before, during, and after subjecting the fibers to a cleaning process designed to remove protein from the surface. *See id.* at 5-8. Dr. Thames analyzed the fibers using light microscopy, SEM, and FTIR at each stage of the cleaning process. *See id.* at 5-12.

The light microscopy and SEM images included in Dr. Thames's report demonstrate that, as the cleaning process progressed, the translucent coating and flakes adhered to the surface of the mesh fibers diminished and ultimately disappeared. *See id.* at 7, 10-12.

The FTIR data of the uncleaned explant fibers show strong carbonyl peaks in the area of the spectrum consistent with proteins. *See id.* at 6-7. Conversely, the FTIR data on explant fibers subjected to the cleaning process—*i.e.*, fibers from which protein was removed—demonstrate that the protein carbonyl peaks disappeared from the FTIR spectrum. *See id.* at 8 (FTIR spectra showing disappearance of carbonyl peaks associated with proteins as cleaning progresses).

In sum, using a scientifically valid and repeatable methodology, Dr. Thames has proven that his cleaning process removed the translucent coating and flakes from the surface of the mesh fibers, and that the translucent coating and flakes were proteins, and not oxidized Prolene as Plaintiffs claim. Importantly, Dr. Thames provided Plaintiffs with his microscopy images and FTIR data in his Report.

Plaintiffs' argument that Dr. Thames should not be permitted to testify about his findings

has no basis in science. As an initial matter, Plaintiffs simply ignore the fact that Dr. Thames formulated his opinions using reliable testing methods that are generally accepted in his field, which are traditional bases for expert opinions. *See Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 592-94 (1993). In addition, Plaintiffs notably fail to acknowledge—much less challenge—the extensive testing Dr. Thames conducted and included in his Report. Furthermore, Plaintiffs are unable to identify any scientific literature, testing, or even opinions from their own experts to support their claims on this issue.

In other words, Plaintiffs' argument appears to have been conceived by Plaintiffs' lawyers without regard for the scientific method, and the Court should reject it on that basis.

V. Plaintiffs Misunderstand the Science Underlying Dr. Thames's Cleaning Protocol.

Plaintiffs assert that Dr. Thames should be precluded from opining about the mesh explants he examined because his "cleaning protocol would have likely destroyed any evidence of oxidation that existed on those meshes." Motion at 8. Plaintiffs also claim that Dr. Thames's testing is unreliable because he "did not even perform a proper control to determine if the cleaning methods he chose would destroy evidence of oxidized polypropylene." *Id.* Once again, Plaintiffs simply misunderstand or ignore the science on which Dr. Thames bases his opinions. Further, Plaintiffs offer no scientific support whatsoever for the contention that the "cleaning protocol would have likely destroyed any evidence of oxidation[.]"

A. Dr. Thames used his knowledge, education, training, and experience as a polymer chemist to develop a cleaning protocol.

As Dr. Thames explains in his Report, proper scientific methodology requires the removal of biological materials, including proteins, from a mesh explant to permit a proper analysis of the mesh fiber itself. *See, e.g.*, Pls.' Motion Ex. C, Thames Report at 15-16. He notes mesh explants are covered with proteins when they are removed from the body, and that the

explants are preserved in formalin, which contains formaldehyde. *Id.* at 11. Dr. Thames advises that a chemical reaction occurs when proteins are exposed to formaldehyde, which results in a "hard, brittle and insoluble" "polymeric shell" adhered to the mesh fibers. *Id.* (observing that the chemistry of formalin fixation has been known and described in the scientific literature since 1949). Thus, the crosslinked formaldehyde-protein shell must be removed before analysis of the mesh. *Id.*

Because no ISO protocol exists for cleaning mesh explants, Dr. Thames used his knowledge of basic organic chemistry to develop a cleaning protocol. Ex. M, Thames Aff. at ¶ 7. Over the course of 25 steps, he placed the formalin-fixed explant in distilled water heated to 70° C, then adds bleach and Proteinase K—an enzyme that denatures proteins. Thames Report at 99-100 (discussing cleaning protocol). Importantly, Dr. Thames's cleaning solution only removes water-soluble substances—like proteins—while leaving the chemical structure of insoluble substances—like oxidized and non-oxidized Prolene—intact. *Id.* at ¶ 10.

Thus, Dr. Thames used a mild cleaning process which reverses the formalin-fixation process, removes proteins adhered to the surface of the mesh fibers, and leaves the mesh fiber available for analysis. *Id.* at ¶¶ 8, 10.

B. The scientific method does not mandate the use of a control in the absence of a variable.

In arguing that Dr. Thames improperly failed to use a control to assess his cleaning protocol, Plaintiffs appear to misapprehend the purpose of a control. As Dr. Thames explains, experimental controls are only necessary to control variables. *Id.* at ¶ 11. Because the solubility characteristics of the substances at issue—*i.e.*, Prolene and/or allegedly oxidized Prolene, proteins, and formalin—are fundamental concepts in chemistry, there is no variable in play. *Id.* at

¶¶ 9-11. In the absence of a variable, proper scientific methodology does not require a control. Plaintiffs cite no scientific evidence to support their assertion to the contrary.

C. Plaintiffs misunderstand the scientific meaning of "carbonyl" peaks and the purpose of Proteinase K.

Turning to Plaintiffs' assertion that Dr. Thames failed to consider the effect of Proteinase K on potentially oxidized Prolene, the scientific evidence shows that Plaintiffs' argument is predicated on a fundamental misunderstanding of the science at issue.

FTIR is an analytical technique that permits scientists to determine the unique chemical composition of a material. Ex. M, Thames Aff. at ¶ 14. It produces spectrum that shows the chemical signature or fingerprint of surface material. *Id.* Specific chemicals in a material manifest in FTIR spectra as a specific band or "peak." *Id.* One such peak is associated with the presence of carbonyl groups, which are structural entities that possess carbon and oxygen atoms. *Id.*; Pls.' Motion Ex. C, Thames Report at 22.

Importantly, Dr. Thames explains that "FTIR spectra may include many different types of carbonyl bands, such as amides, esters, ketones, and aldehydes." Ex. M, Thames Aff. at ¶ 15. Dr. Thames also states that while certain carbonyl bands can be indicative of oxidation, others merely "show other materials present on the surface" of the specimen. *Id.* For this reason, the proper chemical identification of a material requires an understanding of the FTIR signatures for specific substances. Pls.' Motion Ex. C, Thames Report at 22 (reporting that "strong frequencies at 1539, 1653, and 3300 cm^{-1} are indicative of protein(s) and not PP and/or Prolene," and "[c]arbonyl stretching" can "occur[] in the 1830 cm^{-1} to 1650 cm^{-1} region" on FTIR spectra).

Plaintiffs argue that "[a]ccording to Dr. Thames, Proteinase K takes away carbonyls, but carbonyls are also what would be present on the mesh if it was oxidized." Motion at 10. Plaintiffs notably fail to identify any scientific evidence to support their contention that Dr.

Thames's cleaning process removed evidence of oxidation. Rather, they point only to Dr. Thames's deposition, where he testified that Proteinase K removes carbonyl peaks. Motion at 9 (quoting Thames Dep. Tr. 61:16-62:9).

What Plaintiffs fail to understand—perhaps because they did not ask Dr. Thames specific questions at deposition—is that Proteinase K denatures proteins, but has no effect on Prolene fibers, whether oxidized or not. Ex. M, Thames Aff. at ¶¶ 16-18. In other words, Proteinase K assists in the removal of protein carbonyl peaks, not oxidation carbonyl peaks. *Id.* at ¶ 15. For this reason, although Dr. Thames does not dispute that Proteinase K helps "take[s] away carbonyls," Motion at 10, he explains that "Plaintiffs are using the word 'carbonyls' in a very generic sense that misrepresents the chemistry." Ex. M, Thames Aff. at ¶ 15.

Significantly, if the Prolene in the explants had oxidized *in vivo*, oxidation carbonyl peaks with a unique FTIR fingerprint would have formed. *Id.* at ¶ 17; *see also* Pls.' Motion Ex. C, Thames Report at 22-23 (observing that scientific literature shows that oxidized polypropylene has a carbonyl peak at 1740 cm^{-1}). Fundamental principles of chemistry dictate that oxidized Prolene would be neither soluble in water nor affected by Proteinase K, so any oxidation carbonyl peaks would not have been destroyed by Dr. Thames's cleaning process. Ex. M, Thames Aff. at ¶¶ 10, 17. Thus, if any oxidation carbonyl peaks had existed, the FTIR Dr. Thames conducted after each stage in the cleaning process would have included those peaks.

As Dr. Thames's Report demonstrates, however, the only carbonyl peaks in the FTIR spectra associated with this litigation are associated with proteins. *See* Pls.' Motion Ex. C, Thames Report at 106-07, 112-14; *see also* Ex. M, Thames Aff. at ¶ 17.

As has been shown, Plaintiffs fail to base their arguments in scientific evidence of any kind. Accordingly, the Court should deny Plaintiffs' Motion on this issue.

CONCLUSION

For these reasons, the Court should deny Plaintiffs' Motion to Exclude the Opinions and Testimony of Shelby Thames, Ph.D.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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